

DEC - 2 2003

K 032762

**510(k) Summary of Safety and Effectiveness
XiO Radiation Treatment Planning System
Dynamic Conformal**

Submitter Name: Computerized Medical Systems, Inc.

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and Regulatory Affairs or
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Date Summary Prepared: September 2003

Device Trade Name: XiO Radiation Treatment Planning System

Device Common Name: Radiation Treatment Planning System

Device Classification: System, Simulator, Radiation Therapy per
21CFR892.5840

Substantial Equivalence: BrainLAB BrainSCAN Conformal RT Module,
K971367
3D Line DMLC IV - ERGO, K001163

Device Description: The XiO Radiation Treatment Planning system accepts a) patient diagnostic imaging data from CT and MR scans, or from films, and b) "source" dosimetry data, typically from a linear accelerator. The system then permits the user to display and define (contour) a) the target volume to be treated and b) critical structures which must not receive above a certain level of radiation, on these diagnostic images.

K032762

510(k) Summary of Safety and Effectiveness
XiO Radiation Treatment Planning System
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Page 2 of 3

Based on the prescribed dose, the user, typically a Dosimetrist or Medical Physicist can then create multiple treatment scenarios involving the type, number, position(s) and energy of radiation beams and the use of treatment aids between the source of radiation and the patient (wedges, blocks, ports, etc.). The XiO system then produces a display of radiation dose distribution within the patient, indicating not only doses to the target volume but to surrounding tissue and structures. The “best” plan satisfying the prescription is then selected, one that maximizes dose to the target volume while minimizing dose to surrounding healthy volume. The parameters of the plan are output in hard-copy format for later reference and for placement in the patient file.

This Premarket Notification addresses the addition of support for Dynamic Conformal Therapy. Dynamic Conformal is a treatment modality in which radiation beams are continuously shaped to conform to a target while the gantry rotates and the beam is on. In XiO, the user chooses the target, defines structures to avoid, optional margin(s), and treatment angles. XiO then plans a treatment over a specified arc and with specified beam increments, with the leaves of the multi-leaf collimator (MLC) continually reshaping the beam to conform to the target. The target receives a homogenous dose while the structures designated as “avoidance structures” are avoided absolutely.

Dose calculation is performed using existing, validated algorithms within XiO. Determination of dose at the specified angles is calculated in the same way as conventional and asymmetric arc beams; the calculated dynamic beam dose distribution is determined as the sum of multiple fixed beam dose distributions across the specified arc.

Device Intended Use:

The XiO RTP System will continue to be used to create treatment plans for any cancer patient for whom external beam radiation therapy or brachytherapy has been prescribed.

The system will calculate and display, both on-screen and in hard copy, either two- or three-dimensional radiation dose distributions within a patient for a given treatment plan set-up.

K032762

**510(k) Summary of Safety and Effectiveness
XiO Radiation Treatment Planning System
Dynamic Conformal
Page 3 of 3**

Summary of Technological Characteristics Compared to Predicate Devices: Like the XiO Dynamic Conformal feature, the predicate devices are used to generate plans for treatments that use a combination of rotational radiation beams and dynamic MLCs to conform the beam to the target while the gantry rotates and the beam is on.

Both predicate devices (BrainSCAN RTP System with Conformal RT Module and ERGO) are sold with companion micro-MLCs that are directly controlled by the RTP software. The XiO system does not include an MLC and does not directly control the MLC leaves. Instead, XiO exports the leaf positions to any standard linac MLC.

Detailed comparison information can be found in Section 6 of this submittal.

Summary of Clinical Testing: Actual testing in a clinic was not performed as part of the development of this feature. Clinical testing is not required to demonstrate substantial equivalence or safety and effectiveness of the device. Clinically oriented validation test cases were written and executed in-house by CMS customer support personnel.

Summary of Non-Clinical Testing: Algorithm test cases were written and executed to ensure that the system is calculating dose correctly for Dynamic Conformal beams. Results of this testing can be found in the XiO Dynamic Conformal Algorithm Test Report, included in section 9 of this submittal.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Michael A. Parsons
Director, Quality Assurance and
Regulatory Affairs
Computerized Medical Systems, Inc.
1145 Corporate Lake Drive
Suite 100
ST LOUIS MO 63132

Re: K032762
Trade/Device Name: XiO RTP System with Dynamic
Conformal Arc Therapy
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged particle radiation
therapy system
Regulatory Class: II
Product Code: IYE and MUJ
Dated: September 4, 2003
Received September 5, 2003

Dear Mr. Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.


This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

| | |
|----------------------------------|----------------|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indication for Use

510(k) Number: K032762

Device Name: XiO RTP System with Dynamic Conformal Arc Therapy

Indication for use: The XiO RTP System is used to create treatment plans for any cancer patient for whom external beam radiation therapy or brachytherapy has been prescribed. The system will calculate and display, both on-screen and in hard-copy, either two- or three-dimensional radiation dose distributions within a patient for a given treatment plan set-up.

Optionally, the user may elect to generate plans using Dynamic Conformal Arc Therapy capability. Dynamic Conformal Arc Therapy is a treatment modality in which the gantry rotates in an arc (or multiple arcs) over user-specified angles while the leaves of a multi-leaf collimator (MLC) continually reshape the beam to conform to the target.

Concurrence of the Center for Devices and Radiological Health,
Office of Device Evaluation (ODE)

Prescription Use ☒

OR
per 21 CFR 801.109

Over the Counter Use ☐

David A. Legerman

(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K032762